

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION**

IN RE: ABILIFY (ARIPRAZOLE)
PRODUCTS LIABILITY LITIGATION

Case No. 3:16md2734

This Document Relates to:
Hutt, 3:17cv634

Judge M. Casey Rodgers
Magistrate Judge Gary Jones

ORDER

Plaintiff Samantha Hutt, and her parents Ellen and Jeffrey Hutt, brought this action against Defendants, the makers and marketers of Abilify. Plaintiffs allege that Samantha Hutt developed compulsive behaviors after taking Abilify as prescribed, including compulsive gambling, binge eating and hypersexuality. Plaintiffs assert nine claims under Massachusetts law and Defendants have moved for summary judgment on all of them.¹ In their briefing, Plaintiffs failed to address Defendants' arguments regarding their claims for strict liability, breach of express warranty, negligence per se, and fraudulent concealment. Consequently, those claims are considered abandoned and summary judgment will be entered in Defendants' favor. *See Jones v. Bank of Am., N.A.*, 564 F. App'x 432, 434 (11th

¹ The Hutt's direct-filed their complaint in the MDL and assert claims for strict liability, breach of express and implied warranty, negligence, negligence per se, negligent misrepresentation, violation of consumer protection laws, fraudulent concealment and loss of consortium. *See* ECF No. 1 at 5. The Court agrees with the parties that Massachusetts substantive law governs their claims.

Cir. 2014) (“[W]hen a party fails to respond to an argument or otherwise address a claim [in response to a motion for summary judgment], the Court deems such argument or claim abandoned.”). As to the remaining claims, which are all premised on a failure-to-warn theory, the Court finds there exists a genuine dispute of material fact on the sole issue raised by Defendants—whether Plaintiffs’ claims are barred by the learned intermediary doctrine.² Therefore, Defendants’ motion for summary judgment will be denied as to those claims.

Ordinarily, a manufacturer of a product which it “knows or should know is dangerous” has a duty to warn foreseeable users of the dangers associated with using the product. *MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 135 (1985); *see also Laaperi v. Sears, Roebuck & Co., Inc.*, 787 F.2d 726, 729 (1st Cir. 1986). Massachusetts law carves out a “middleman” exception to this rule that allows pharmaceutical manufacturers to discharge their duty to warn consumers by adequately informing prescribing physicians—as opposed to patients directly—of any risks associated with their prescription drug products.³ *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992). Where a manufacturer breaches the duty to

² In Plaintiffs’ brief, they request that Rule 11 sanctions be imposed against Defendants for filing the instant summary judgment motion. *See* ECF No. 33 at 21-25. Because Plaintiffs did not comply with the procedural prerequisites for seeking sanctions, their request is denied.

³ “The rationale underlying [this] rule is that the prescribing physician, as the ‘learned intermediary’ standing between the manufacturer and consumer/patient, is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly.” *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992).

warn a physician, however, it is directly liable to the patient. *MacDonald*, 394 Mass. at 136.

Massachusetts courts employ a burden-shifting framework in determining whether a plaintiff can establish a prima facie case of failure-to-warn when a defendant invokes the learned intermediary doctrine. Under this framework,

(1) the plaintiff carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known; (2) assuming the plaintiff raises a triable issue on this question, a rebuttable presumption arises that the physician would have heeded an adequate warning; (3) defendant must then come forward with sufficient evidence to rebut that presumption; and (4) once the presumption is rebutted, plaintiff must produce sufficient evidence to create a triable issue on the question of causation.

Garside, 976 F.2d at 81 (internal marks omitted).

Here, for purposes of summary judgment, Defendants “assume[d] that Plaintiffs can meet their initial burden of showing that the Abilify warning was inadequate because it did not warn about compulsive behaviors while Samantha was on the drug, and that a rebuttable presumption therefore arises that Dr. Wozniak[, her physician,] would have heeded such a warning.” *See* ECF No. 28-20 at 20-21. The Court will do the same. Additionally, the Court will assume without deciding that Defendants can come forward with sufficient evidence to rebut that

presumption.⁴ Thus, the only question to be resolved is whether Plaintiffs produced sufficient evidence to create a triable issue on causation. The Court finds that they have.

Briefly, Plaintiffs produced an email showing that Dr. Wozniak learned about the association between Abilify and compulsive gambling, eating, shopping and sexual activity from an FDA News Alert on May 3, 2016. *See* ECF No. 33-5. Dr. Wozniak emailed the alert to Ellen Hutt within 15 minutes of receiving it, expressed her belief that Samantha’s compulsivity problems were “Abilify-induced” and apologized “for likely prolonging [Samantha’s] disability” by prescribing her the drug and never suspecting that Abilify could be responsible for her “risky behaviors.” *See id.* at 2. A jury could reasonably infer from Dr. Wozniak’s actual response to the FDA’s warning—that is, recognizing that Samantha “likely” suffered

⁴ The Court has serious reservations about whether the evidence cited by Defendants is sufficient to rebut the presumption, given Dr. Wozniak’s equivocation—offered in hindsight, years after her Abilify prescribing decisions for Samantha—about what she would have done if she had received an adequate warning. However, the Court need not definitively resolve that question because Plaintiff has plainly come forward with sufficient evidence to create a triable fact on the issue of causation. *See Garside*, 976 F.2d at 83, n.9 (finding based on Massachusetts failure-to-warn jurisprudence that “the Massachusetts Supreme Judicial Court would likely be reluctant to allow a physician’s pre-trial testimony about what s/he would have done had s/he been warned to insulate a manufacturer from liability”); *see also Doe v. Miles Lab., Inc.*, 927 F.2d 187, 195 n.32 (4th Cir. 1991) (applying Maryland law) (“Although [the physician] testified that she would have administered the drug regardless of the AIDS risk, her hindsight opinion is not conclusive of what she would have done had she been invested with all the pertinent facts regarding [the drug]. Thus, the causation issue . . . presents a genuine issue of material fact.”); *Williams v. Lederle Lab.*, 591 F. Supp. 381, 386 (S.D. Ohio 1984) (applying Ohio law) (“What [the physician might or might not have done involves to some degree his credibility. Thus, we conclude that it is for the jury to determine whether the presence of an adequate warning would have made no difference in [the physician’s] decision.”).

dangerous side effects from Abilify and immediately communicating the warning to Samantha's mother—that she would have heeded an adequate warning about the potential dangers of Abilify, if given at the time of her prescribing decisions for Samantha. This reasonable inference is bolstered by evidence that Dr. Wozniak changed Samantha's treatment regimen numerous times before in response to risk warnings on other prescription drug labels and/or when Samantha experienced adverse labeled side effects from a drug, such that a jury could reasonably infer that the doctor would have followed that same practice in response to warnings about potential adverse side effects from Abilify. Contrary to Defendants' assertion, Dr. Wozniak's deposition testimony that she cannot now say what she might or might not have done years ago in the presence of an adequate Abilify warning does not overcome the uncontroverted evidence supporting a conclusion that she would have heeded any such warning. In short, the evidence is more than sufficient to create a triable issue as to whether Defendants' alleged failure to provide an adequate warning was the proximate cause of Plaintiffs' injuries. Therefore, Defendants are not entitled to summary judgment on the claims premised on a failure-to-warn.

Accordingly:

1. Defendants' Motion for Summary Judgment, ECF No. 28, is **GRANTED IN PART** and **DENIED IN PART**, as follows:
 - a. The motion is **GRANTED** with respect to Count I (strict liability), Count II (breach of express warranty), Count V (negligence per se), and Count VIII (fraudulent concealment).

- b. The motion is **DENIED** with respect to Count III (breach of implied warranty), Count IV (negligence), Count VI (negligent misrepresentation, Count VII (violation of Massachusetts consumer protection laws, and Count IX (loss of consortium).
2. With the entry of this Order, all pretrial proceedings in this direct-filed case are complete and the case is ready for trial. By separate order, the case will be transferred to its proper venue, the District of Massachusetts, for trial.

SO ORDERED, on this 6th day of January, 2020.

M. Casey Rodgers

M. CASEY RODGERS
UNITED STATES DISTRICT JUDGE